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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/059,080	01/30/2002	Edward O. Kenaschuk	80694-502	5731

23529 7590 07/03/2003

ADE & COMPANY  
1700-360 MAIN STREET  
WINNIPEG, MB R3C3Z3  
CANADA

EXAMINER
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MCELWAIN, ELIZABETH F

ART UNIT	PAPER NUMBER
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1638

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DATE MAILED: 07/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application N .	Applicant(s)
	10/059,080	KENASCHUK, EDWARD O.
	Examiner Elizabeth F. McElwain	Art Unit 1638

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) Responsive to communication(s) filed on 25 April 2003.
- 2a) This action is **FINAL**.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) Claim(s) 1-9 and 13 is/are pending in the application.
  - 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1-9 and 13 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
 

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
 

If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
  - a) All    b) Some \*    c) None of:
    1. Certified copies of the priority documents have been received.
    2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
    3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
  - a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)
3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____	6) <input type="checkbox"/> Other: _____

The amendment filed April 25, 2003 has been entered.

Claims 10-12 and 14 have been cancelled.

Applicant's election without traverse of Group I, claims 1-9 and 13, in Paper No. 5 is acknowledged.

5 Claims 1-9 and 13 are pending and are examined in the present office action.

The specification is objected to for the inclusion of tables on numbered pages after the claims and abstract. The tables should be provided on pages that are part of the specification prior to the claims. Alternatively, these pages could be cancelled and the tables could be  
10 submitted as drawings, and as drawings would require a written description of each drawing in the specification.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

15 The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 3, 6, 7-9 and 13 are rejected under 35 U.S.C. 112, second paragraph, as being  
indefinite for failing to particularly point out and distinctly claim the subject matter which  
applicant regards as the invention.

Claims 3, 6, 7-9 and 13 are indefinite in the recitation of "M5791" given that a name  
20 does not clearly identify the claimed flax cultivar and seed, and does not set forth the metes  
and bounds of the claimed invention. Since the name M5791 is not known in the art, the use of  
said name does not carry art recognized limitations as to the specific characteristics or essential

characteristics which are associated with that denomination. In addition, the name appears to be arbitrary and the specific characteristics associated therewith could be modified, as there is no written description of the flax plant that encompasses all of its traits. Amending the claims to recite the ATCC (or other seed depository) deposit number would overcome the rejection.

5 Claim 9 is indefinite in that "seeds" and "plants" are plural, so that it appears that the claim is improperly multiple dependent. The amendment of the claim to read "seed from the flax plant of any one of claims 4, 5, 6, 7 or 9" would overcome the rejection.

Claim 13 is indefinite in the recitation of "descendant", which appears to be a misspelling of "descendant".

10

The following is a quotation of the first paragraph of 35 U.S.C. 112:

15 The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

20 Claim 3 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claim is drawn to a flax seed that is the product of a plant line designated M5791. However, no written description of the product is provided, and the seed product may be the product of numerous crosses with unidentified flax cultivars. The

claimed seeds are not defined by genomic structure or by phenotypic characteristics, and therefore, the claimed invention lacks an adequate written description.

See *University of California v. Eli Lilly*, 119 F.3d 1559, 43 USPQ 2d 1398 (Fed. Cir.

5 1997), where it states:

10 “The name cDNA is not in itself a written description of that DNA; it conveys no distinguishing information concerning its identity. While the example provides a process for obtaining human insulin-encoding cDNA, there is no further information in the patent pertaining to that cDNA’s relevant structural or physical characteristics; in other words, it thus does not describe human insulin cDNA . . . Accordingly, the specification does not provide a written description of the invention . . .”

15 Therefore, given the lack of written description in the specification with regard to the structural and physical characteristics of the claimed compositions, one skilled in the art would not have been in possession of the genus claimed at the time this application was filed.

20 Claims 2, 3, 5-9 and 13 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

25 Since the M5791 seed claimed is essential to the claimed invention, it must be obtainable by a repeatable method set forth in the specification or otherwise be readily available to the public. If a seed is not so obtainable or available, the requirements of 35

U.S.C. 112 may be satisfied by a deposit thereof. The specification does not disclose a repeatable process to obtain the exact same seed in each occurrence and it is not apparent if such a seed is readily available to the public. If the deposit of these seeds is made under the terms of the Budapest Treaty, then an affidavit or declaration by the applicants, or a statement 5 by an attorney of record over his or her signature and registration number, stating that the seeds will be irrevocably and without restriction or condition released to the public upon the issuance of a patent would satisfy the deposit requirement made herein. A minimum deposit of 2500 seeds is considered sufficient in the ordinary case to assure availability through the period for which a deposit must be maintained.

10 If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit, meets the criteria set forth in 37 CFR 1.801-1.809, applicants may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number showing that

15 (a) during the pendency of the application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

(c) the deposit will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the enforceable life of the patent, whichever is longer;

20 (d) the viability of the biological material at the time of deposit will be tested (see 37 CFR 1.807); and

(e) the deposit will be replaced if it should ever become inviable.

Claims 2, 5, 8 and 13 are rejected under 35 U.S.C. 112, first paragraph, because the  
5 specification, while being enabling for the flax cultivar M5791 with seeds having greater than  
70% linolenic acid but not more than 73% linolenic acid, that is flax cultivar M5791 or a  
progeny of M5791 does not reasonably provide enablement for any flax cultivar having greater  
than 70% linolenic acid. The specification does not enable any person skilled in the art to  
which it pertains, or with which it is most nearly connected, to the invention commensurate in  
10 scope with these claims.

The specification only discloses flax cultivar M5791 having 70-73% linolenic acid.  
The specification does not disclose any other flax cultivars that have that level of linolenic acid  
or any other means of producing another flax cultivar having that level of linolenic acid. In  
fact, the specification discloses that other known flax cultivars typically have 58% linolenic  
15 acid. The specification also teaches that to produce the flax cultivar M5791 having 70-73%  
linolenic acid, it required six crosses and selection steps using at least six cultivars (see pages  
11-12). However, from the information presented in the specification it is unclear what  
specific crosses were made and in what order to achieve the high linolenic acid flax M5791.

Given the recognition of those skilled in the art of plant breeding of the inherent  
20 unpredictability of producing modified characteristics in a plant, given the absence of guidance  
of other means of producing the same effect, the lack of working examples of other high

linolenic acid flax cultivars, and in view of the breadth of the claims which encompass any flax cultivar having greater than 70% linolenic acid, and in view of the state of the art which taught flax varieties having no more than 65.5% linolenic acid (see PI 524302 and PI91037), it would require undue experimentation by one skilled in the art to make and/or use the invention, as 5 broadly claimed.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

10 (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by PI 524302.

15 The claims are drawn to a flax cultivar having at least 65% linolenic acid.

PI 524302 teaches a flax cultivar having at least 65% linolenic acid.

Claims 1 and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by PI 91037.

The claims are drawn to a flax cultivar having at least 65% linolenic acid.

20 PI 91037 teaches a flax cultivar having at least 65% linolenic acid.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth F. McElwain whose telephone number is (703) 308-1794. The examiner can normally be reached on Monday through Friday from 8:00 AM to 4:30 PM.

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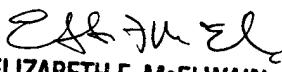
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218. The fax phone number for this Group is (703) 308-4242. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989).

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Any inquiry of a general nature or relating to the status of this application should be directed to the CUSTOMER SERVICE TECH CENTER 1600, whose telephone number is (703) 308-0198, or to the Group receptionist whose telephone number is (703) 308-0196.

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Elizabeth F. McElwain, Ph.D.  
June 30, 2003

  
ELIZABETH F. McELWAIN  
PRIMARY EXAMINER  
GROUP 1600